DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

December 2, 2002

WARNING LETTER NYK 2003-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles L. Earsing, Owner
Charles L. Earsing Dairy Farm
3928 Broadway Road, Route 20
Alexander, NY 14005-9781

Dear Mr. Earsing:

An investigation was conducted at your dairy farm operation located behind 3971 Broadway Road and adjacent to 3928 Broadway Road, Alexander, NY, by U.S. Food and Drug (FDA) Investigators William P. Chilton and Harry J. Brewer on August 27-30, 2002. The investigation confirmed that you offered two cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act); and that you have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about February 28, 2002, you sold a cow to [redacted], where sale tag No. 627 and back tag No. 21NG3038 were attached to the cow. This cow was subsequently delivered to and slaughtered at [redacted] on or about March 1, 2002. USDA analysis of tissue samples from that animal revealed the presence of the drug sulfadimethoxine at a level of 14.81 ppm in the liver and 7.70 ppm in the muscle. These levels exceed the 0.1 ppm tolerance identified in 21 Code of Federal Regulations (CFR) 556.640 by more than 148 times and 77 times, respectively. USDA analysis of tissue samples from that animal also revealed the presence of the drug flunixin at a level of 1.38 ppm in the liver. This level exceeds the 0.125 ppm tolerance identified in 21 CFR 556.286. The presence of sulfadimethoxine and flunixin at these levels in cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about April 29, 2002, you sold a cow to [redacted], where sale tag No. 83 and back tag No. 21NG5049 were attached to the cow. This cow was subsequently delivered to and slaughtered at [redacted] on or about April 30, 2002. USDA analysis of tissue samples from that animal revealed the presence of the drug flunixin at a level of 0.18 ppm in the liver. This level exceeds the 0.125 ppm tolerance identified in 21 CFR

556.286. The presence of flunixin at this level in cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about May 30, 2001, you provided [redacted], a signed Livestock Owners' Certificate. This certificate certified that none of the livestock are adulterated within the meaning of the Federal Food, Drug and Cosmetic Act, i.e., have an illegal level of drug residues. On or about February 28, 2002 and April 29, 2002 you sold these cows adulterated with these residues to [redacted]

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Our investigation also revealed you adulterated the drugs sulfadimethoxine and flunixin within the meaning of Section 501(a)(5) of the Act when you used the drugs in an extralabel manner without veterinary supervision. Your failure to follow veterinary withdrawal instructions before offering the cows for slaughter causes the drugs to be unsafe to use.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may results in regulatory action – without further notice. This may include seizure and injunction.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. As a dairy farmer, you are the individual who introduces or offers for introduction into interstate commerce the adulterated animals. It is not necessary for you to personally ship an animal into interstate commerce to be responsible for violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken, or intend to take, to prevent recurrence of these or similar violations. Your response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

Jerome G. Woyshner/ca

Jerome G. Woyshner
District Director